

Remarks

Claims 1, 4-7, and 19-20 are currently pending. No claims have been allowed. Claim 5 has been amended herein.

Claims 1-7, 19 and 20 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the rejection appears to be centered around the concept of undue experimentation, and the *In Re Wands* factors are cited in support thereof.

Applicants traverse this rejection.

The *In re Wands* factors include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The MPEP at 2164.01 provides further guidance:

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed

invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Based on the Examiner's comments, it would appear that she is basing her conclusion mainly on the breadth of the claims (page 5, "Thus, the scope is very broad."), with little or no consideration of the other factors, aside from incorrectly characterizing the skilled artisan as a physician, when the skilled artisan with respect to the compound claims, would clearly be a medicinal chemist with experience in small molecule synthesis. Indeed, it is contemplated that a multiplicity of skilled artisans may be necessary to practice a complex invention:

When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. "If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures." *Technicon Instruments Corp. v. Alkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Orc. 1986), aff'd in part, vacated in part, rev'd in part, 837 F. 2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F. 2d 417, 9 USPQ 2d 1540 (Fed. Cir. 1989). In *Ex parte Zechnall*, 194 USPQ 461 (Bd. App. 1973), the Board stated "appellants' disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants' invention." 194 USPQ at 461.

MPEP at 2164.05(b)

Thus, in the instant case, a medicinal chemist is the correct skilled artisan for the currently pending compound claims, whereas it is possible that a physician may be the artisan of choice for method of treatment claims (which are not currently under consideration).

Leaving aside the issue as to whether Examiner's burden has been met by her cursory assessment of only some of the Wands factors, Applicants wish to point out that the extensive list of compounds listed from page 12, line 14, to page 17, line 8, exhibit activity in the assays, as discussed on page 96. Therefore, the breadth of the claims is amply supported by physiological activity in the patch clamp and AAS assay.

The Examiner further cites *In re Surrey* (370 F. 2d, 349, CCPA, 1966), but Applicants note that *Surrey* finds agreement with Applicants' contentions that the methods of preparation and use, as supported by the specification would permit any chemist to synthesize any compound falling within the scope of the claims (citing *In re Grimme*, 274 F.2d 949, 47 CCPA 785: "It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it.").

The balance of the Wands factors support Applicants' position that the claims are enabled. Specifically, the specification provides ample guidance and data covering a long list of specific compounds, all of which perform in the assays at physiological levels. The level of skill in the art is very high, as the artisan would be a highly trained medicinal chemist with experience in structure-activity relationships. The MPEP further states that:

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

MPEP, 2164.01

Based on the foregoing, Applicants assert the claims are enabled and in condition for allowance. If a telephonic communication will advance the prosecution of the instant application, please telephone Applicants' representative indicated below. Applicants believe no additional fees are due, but the Commissioner is authorized to charge any fees required in connection with this amendment to Merck Deposit Account No. 13-2755.

Respectfully submitted,

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Date: March 10, 2009